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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,425	07/31/2001	Bruce B. Lee	M-11515 US	5907

32605 7590 12/16/2003

MACPHERSON KWOK CHEN & HEID LLP :
1762 TECHNOLOGY DRIVE, SUITE 226
SAN JOSE, CA 95110

EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,425

Applicant(s)

LEE, BRUCE B.

Examiner

Peter J Vrettakos

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-17 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-17, and 19-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1,2, 6-13, 16,19-23, and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Behl ('433) and further in view of Edwards et al. ('123).

Re: independent claim 1 and dependent claims 7,9,20,22, Savage et al.
(Savage) discloses especially in figure 3 a method and system (40) for treating a pelvic tumor (can be in the uterus; column 2 line 33) comprising insertion into a pelvic region (shaded), positioning the ablation device (30) proximate the pelvic tumor (T), confirming the placement of the ablation device with a laparoscope (column 5 lines 33-36) and an ultrasound imaging device including a monitor (46; column 5 lines 43-49), and delivery of RF energy by electrode coupled to a RF energy source (42) through the ablation device (column 5 lines 38-43) to ablate the tumor.

Re: claim 8, Savage discloses ultrasound imaging (46,32; column 5 lines 43-45) of the tumor in figure 3. Element 48 represents the image plane. From this illustration and through routine experimentation, one could determine optimal placement of the incision through which the ultrasound device is received (top, bottom, etc.)

Savage, which has been described above, neglects to disclose insertion of the ablation device directly into the tumor and a plurality of deployable arms.

Behl discloses a tumor ablation device (20; fig. 2) that is inserted into a tumor (T) as illustrated in figure 6c. Moreover, Behl discloses a plurality of deployable **(from the tip of the ablation device)** electrode arms (32; figures 3 & 6c; column 10 lines 21-24.)

Re: independent claims 12, 27 and claim 13, taken in combination with remarks above regarding independent claim 1 a 35 USC § 103 rejection is appropriate as optimal (assuming the applicant's assertions are optimal) placement of the monitor, the energy source, imaging device, and the patient in the operating room could be determined through routine experimentation or harmless trial and error. Further, the examiner contends that the disclosed placement is obvious to any surgeon that normally deals with similar equipment during similar surgeries and that the specification is silent regarding statements of criticality or unexpected results that could arise from the disclosed placement.

Re: claim 16, repositioning the uterus relative to the ablation device, as a method step would be determined through harmless trial and error by the average surgeon upon performing the surgery if conditions called for it.

Re: claim 25, it would also have been obvious that if more than one tumor was present, both would be treated sequentially.

Re: claims 10,11,23, and 30, through routine experimentation the optimal tumor size, ablation temperatures and time of application could be determined.

Several of the applicant's claims include steps that have been deemed obvious. The applicant to appropriately address these rejections should provide arguments that posit statements of criticality. In other words, indicate how the steps are essential to the efficacy of the surgery and why would those steps not be obvious or easily determined through routine experimentation or harmless trial and error.

Savage and Behl, neglect to disclose complete insertion of the electrodes into the targeted tumor.

Edwards et al. (Edwards) discloses an analogous tumor treatment system and method in which the device electrode is inserted completely within the targeted tumor (154) as depicted in figure 15.

Therefore, it would have been obvious from Savage in view of Behl and further in view of Edwards that through routine experimentation parameters of tumor size, ablation temperature, time of application, incision placement, and operating room configuration could be determined. The motivation would be to provide an optimal uterine tumor ablation protocol.

Further, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Behl and further in view of Edwards by including a plurality of deployable electrode arms as a design expedient as well as complete insertion of the device electrode into the targeted tumor. The motivation would be to uniformly generate

heat throughout a desired target tissue volume through the use of symmetrically spaced apart electrodes as disclosed in Behl column 1 lines 36-39. The nexus between Savage and Behl is found in Behl col. 4:20-24 and 37-47. Behl's "two-step method" in col. 4:43-44 includes as a first step targeting blood flow to the targeted tumor prior to targeting the tumor itself. This first step is analogous to Savage's disclosed protocol. The motivation for complete insertion of the electrode into the targeted tumor would be to minimize damage of healthy peripheral tissue due to the heat generated by the electrode.

2. Claims 3,4, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Burbank et al. ('601).

Savage, Behl, and Edwards, which have been described above, neglect to *explicitly* disclose insertion of the device through the cervix or abdomen.

Burbank discloses a uterine tumor ablation protocol in which the ablation device is inserted transvaginally (through the cervix), as well as retroperitoneally (through the abdomen) Note abstract.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Behl and further in view of Edwards and further in view of Burbank by accessing the uterus by traversing the cervix. The motivation would be to provide a

minimally invasive route to the tumor and by traversing the abdomen to provide an alternate route.

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Burbank and further in view of Schmaltz et al ('383).

Savage, Behl, Edwards, and Burbank, which have been described above, neglect to disclose rotation of the device during insertion.

Schmaltz et al. (Schmaltz) discloses a rotatable electrode device (10) for treatment of uterine tumors. The device rotates to facilitate entry and passage through tissue such as abdominal. Note column 3 lines 3-5.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Behl and further in view of Edwards and further in view of Burbank and further in view of Schmaltz by including a rotatable ablation device. The motivation would be to facilitate entry and passage through tissue as disclosed by Schmaltz column 3 lines 3-5.

4. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Savage in view of Behl and further in view of Edwards and further in view of Moorman et al. ('033).

Savage, Behl, and Edwards, which have been described above, neglect to disclose cauterizing the withdrawal track of the ablation device. Note column 12 lines 16-21.

Moorman et al. discloses cauterizing the withdrawal track of the ablation device.

Therefore, it would have been obvious to one of ordinary skill in the art to modify Savage in view of Behl and further in view of Edwards and further in view of Moorman et al. by cauterizing the withdrawal track of the ablation device. The motivation would be to reduce bleeding and to kill any displaced tumor cells.

Response to Amendments

Applicant's amendments to claims 1-4,6-17, and 19-30 have been considered.

Applicant's arguments filed 9-14-03 have been fully considered but they are not persuasive. The Applicant claims that the combination of Edwards et al. to Savage and Behl would destroy the intended function of Savage and Behl. This might be true (insertion of electrodes for ablating *into* a tumor is not equivalent to placing electrodes *adjacent* a tumor to treat blood supply) in a vacuum. However, one must consider the context in which the prior art and the application are found. Both groups involve ablative treatment of a tumor. Generally, this means that energy is applied to the body with the purpose of shrinking/destroying a tumor. Surgeons are fully aware of different techniques (ex. placement of electrodes) to shrink tumors with ablative energy and can take the approach that "there is more than one way to skin a cat." Insertion of electrodes into a tumor or adjacent a tumor for the purposes of destroying that tumor are simply too

close as techniques/protocols/methods to claim that one is not obvious in light of the other. To this end, the Examiner respectfully submits that the combination of the prior art is valid, and in the contexts in which the methods are found (destroying a tumor), are seamlessly combinable, especially to a medical professional who often undertakes these types of surgeries.

Regarding the limitation toward a single puncture site, which serves as the point at which substantially the entire tumor is ablated, the reader is directed to figure 1 in Behl. Deployable electrodes (12) are depicted substantially inside of a tumor. It is clear that at the tip of element (10) emanates all of the electrodes. This emergence point is where the concentration of the electrodes is highest (and therefore the ablative energy). With that said, it can be concluded that in figure 1 from a single "puncture" (tip) site substantially all of the tumor is ablated (at a sufficient power).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone numbers for the organization where this application or proceeding is assigned are 703 746 7013 for regular communications and 703 746 7013 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

Pete Vrettakos
December 4, 2003

PV



LINDA C. M. DVORAK
SUPERVISORY PATENT EXAMINER
GROUP 3700